UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

GILDA HAGAN-BROWN Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	CASE NO.: 1:14-CV-01614
JANINE ALI Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	CASE NO.: 1:14-CV-01615

REPLY MEMORANDUM IN SUPPORT OF
DEFENDANT'S MOTION FOR JUDGMENT ON THE PLEADINGS

PRELIMINARY STATEMENT

Plaintiffs have conceded that their design defect claims are preempted and have withdrawn them. That should be the end of this matter. The Court should enter an order effecting Plaintiffs' concession that dismisses their design defect claims with prejudice.

Rather than confront the implications of their concession, Plaintiffs spend the bulk of their "Response" trying to explain how, even though their design defect claims are preempted, they should nevertheless be able to recast those design defect theories as failure-to-warn claims. Amending their complaints to slap a different title on the same core design defect claims would be futile, as the substance of those claims would still be preempted. Plaintiffs' request to amend is also procedurally improper because Plaintiffs have failed to follow the normal channels for requesting leave and have brought their request in an untimely manner — just a few weeks shy of the close of discovery.

The Court should also deny Plaintiffs' request to conduct a Rule 30(b)(6) deposition on capsule design topics. Recasting the design claims as failure-to-warn claims does not change their fundamental character. Indeed, Plaintiffs pressed this argument to Judge Anderson at the recent hearing on their motion to compel and, as Judge Anderson recognized, Plaintiffs' proposed technical design topics have no relevance to their failure-to-warn claims. Plaintiffs are free to ask questions related to their warning theories with the many witnesses Lilly is presenting for deposition, but, as Judge Anderson has already ruled, Lilly should not be forced to undergo the burden and expense of preparing a witness on claims that Plaintiffs concede are preempted.

Because Plaintiffs have conceded that their design defect claims are not legally viable and that Lilly's motion should be granted, Lilly respectfully submits that the May 1, 2015 hearing is now no longer necessary and that the Court should grant Lilly's motion on the papers.

LEGAL ARGUMENT

I. Amendment Would Be Futile Because Plaintiffs' Proposed Amendments Would Also Necessarily Fail as a Matter of Law.

In their response to Lilly's motion for judgment on the pleadings, Plaintiffs concede that their design defect claims are preempted and purport to withdraw them. *See* Pls.' Response at 1, 9. They then ask the Court to grant them leave to amend their complaints to recast their design claims as new failure-to-warn allegations on the eve of the close of discovery.[1] This motion for leave to amend, which Plaintiffs masquerade as a "request for guidance," Pls.' Response at 2, 9-10, should be denied for the simple reason that amendment would be futile. *See, e.g., Equal Rights Ctr. v. Niles Bolton Assocs.*, 602 F.3d 597, 603 (4th Cir. 2010) (leave to amend should be denied where "amendment would be futile"); *Perkins v. United States*, 55 F.3d 910, 917 (4th Cir. 1995) (affirming denial of motion to amend as futile where "the proposed amendments could not withstand a motion to dismiss"). Plaintiffs suggest in their response that they can avoid preemption simply by re-casting their non-viable design defect claims as failure-to-warn claims. *See* Pls.' Response at 4-7, 9. This assertion has no basis in law. Whether presented as design defect claims or as failure-to-warn claims, Plaintiffs' insistence that Lilly can be held to pay damages for not marketing a different formulation or dosage of Cymbalta cannot be reconciled

[1] Plaintiffs may no longer amend as a matter of right because more than 21 days have elapsed since Lilly filed its answers in these cases. *See* Fed. R. Civ. P. 15(a)(1) ("A party may amend its pleading once as a matter of course within: (A) 21 days after serving it, or (B) if the pleading is one to which a responsive pleading is required, 21 days after service of a responsive pleading or 21 days after service of a motion under Rule 12(b), (e), or (f), *whichever is earlier*.") (emphasis added); *City of New Martinsville v. Pub. Serv. Comm'n*, 2013 U.S. Dist. LEXIS 71808, at *6-7 (S.D. W. Va. May 21, 2013) (leave to amend required where more than 21 days have elapsed since answer, even if defendant subsequently files Rule 12 motion).

with Supreme Court precedent, and these allegations, however captioned, are preempted by federal law.[2]

As an initial matter, the rule articulated in the Supreme Court's decisions in the *Mensing* and *Bartlett* cases could not be more clear: a manufacturer of a prescription medicine may not be forced through the prospect of paying damages in a state-law cause of action to take action it could not unilaterally take under federal law. Pursuant to this principle, a plaintiff may not use state law as a means of forcing a manufacturer to redesign a prescription medicine, as Plaintiffs' design defect claims seek to do here. *See PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2580-81 (2011) ("To decide these cases, it is enough to hold that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes."); *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2479 (2013) ("[W]e hold that state-law design-defect claims like New Hampshire's that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling."). Plaintiffs cannot cure this problem simply by giving a new name to their design defect claims.

[2] Plaintiffs assert in their response that Lilly "does not dispute" that their failure-to-warn claims are "valid." *See* Pls.' Response at 4. This is false. Although Plaintiffs' failure-to-warn claims are not the subject of Lilly's motion for judgment on the pleadings, Lilly denies the validity of those claims, both legally and factually. Indeed, Lilly has successfully sought summary judgment on Plaintiffs' warning claims in this very litigation. *See McDowell v. Eli Lilly & Co.*, — F. Supp. 3d —, 2014 WL 5801604, at *15 (S.D.N.Y. 2014) ("Taken together, the Cymbalta warning is adequate as a matter of law because it is accurate, clear, consistent on its face and portrays with sufficient intensity the risk involved in taking the drug.").

As support for their re-casting argument, Plaintiffs maintain that, pursuant to the Supreme Court's *Wyeth v. Levine* decision, a pharmaceutical manufacturer may invoke the "Changes Being Effected" ("CBE") regulation, 21 C.F.R. § 314.70(c)(6)(iii), to unilaterally add new warnings describing supposed defects in its medicine's design. *See* Pls.' Response at 4-5 (citing *Wyeth v. Levine*, 555 U.S. 555 (2009)).[3] However, Plaintiffs continue to ignore the key principle that the CBE process can be invoked only in the narrow circumstance where "newly acquired information" "not previously submitted to the [FDA]" demonstrates that a medicine's label should be updated to reflect certain narrowly-defined categories of new risk information. *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 41-42 (1st Cir. 2015) (quoting 21 C.F.R. § 314.70(c)(6)(iii)). And these limited categories of new risk information do not include technical descriptions of a medicine's composition or information concerning theoretical alternative designs. *See* 21 C.F.R. § 314.70(c)(6)(iii) (describing limited categories of "newly acquired information" that may be added to label through CBE procedure). The CBE process thus cannot be employed as a means of adding information to the label that the manufacturer submitted to the FDA for its consideration prior to the medicine's initial approval. *See In re Celexa*, 779 F.3d at 41 ("To the extent that the underlying policy issue is one of who decides whether and how a drug can be marketed, the line so drawn lets the FDA be the exclusive judge

[3] In their response, Plaintiffs make the remarkable suggestion that *Levine* was somehow a design defect case. *See* Pls.' Response at 5. Such a suggestion cannot be squared with even a cursory reading of *Levine*. *See Levine*, 555 U.S. at 560-61 (describing the *Levine* plaintiff's claims as "failure-to-warn claims"). Indeed, the word "design" appears only five times in the opinion, and never in reference to the plaintiff's claims. To the contrary, the First Circuit drew this precise distinction in the *Bartlett* case, noting that *Levine* and *Mensing* were failure-to-warn cases and thus did not dictate the outcome in design defect cases: "[I]t is up to the Supreme Court to decide whether *PLIVA*'s exception is to be enlarged to include design defect claims." *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 37-38 (1st Cir. 2012) (also noting that *Levine*'s holding was "limited to failure-to-warn claims"). Of course, the Supreme Court did just that when it reversed the First Circuit's ruling. *See Bartlett*, 133 S. Ct. at 2480.

of safety and efficacy based on information available at the commencement of marketing . . . . *Wyeth* effectively reserves the launch of new drugs to the expertise of the FDA[.]").

In this case, Cymbalta's composition — 20-, 30-, and 60-milligram capsules — has been unchanged since the medicine was first launched in 2004. This fact is reflected in the product's judicially noticeable launch label, *see* Cymbalta Package Insert (Aug. 2004 version), Ex. 1 to the Declaration of Jeffrey T. Bozman ("Bozman Decl."), and Plaintiffs do not allege otherwise in their complaints. Thus, because all aspects of the medicine's design were submitted to the FDA and assessed by the Agency prior to approval, Lilly could not unilaterally invoke the CBE process to add new information to the label concerning the medicine's formulation, Plaintiffs' proposed alternative designs, or any other allegedly defective aspect of the medicine's dosage form or composition. Accordingly, Plaintiffs cannot avoid preemption through nomenclature, and any effort by Plaintiffs to recast their design defect allegations as failure-to-warn allegations would thus necessarily fail as a matter of law.[4]

II. Plaintiffs' Request for Leave to Amend Is Procedurally Improper.

Plaintiffs' request for leave to amend their complaints to plead new (and unspecified) failure-to-warn allegations should also be denied for the separate reason that their request is procedurally improper in two respects.

[4] To the extent Plaintiffs seek to prove that Lilly provided inadequate warnings on tapering or discontinuation, which Lilly denies, such allegations are outlined elsewhere in Plaintiffs' complaints and have been the subject of extensive discovery, and thus require no amendment. *See Ali* Complaint, Dkt. No. 1, ¶¶ 53-68 (failure-to-warn allegations: "Cymbalta was defective and unreasonably dangerous when it left the possession of Lilly in that it contained instructions insufficient to fully inform users and physicians on how to stop Cymbalta[.]"); *Hagan-Brown* Complaint, Dkt. No. 1, ¶¶ 53-69 (same). Those allegations also have nothing to do with the technical design of the Cymbalta capsule or theoretical alternative designs and therefore require no discovery on such irrelevant issues.

First, Plaintiffs have chosen the wrong vehicle — their response to another party's motion seeking dismissal of existing claims — to request leave to amend their complaint to add new allegations that they describe only in vague terms. When a party seeks to amend its pleadings, the proper procedure is to file a motion for leave to amend under Rule 15(a)(2) that includes the proposed amendments and provides the opposing party with ample time to respond pursuant to a customary briefing schedule. *See, e.g.*, Fed. R. Civ. P. 15(a)(2); *Nemphos v. Nestle Waters N. Am., Inc.*, 775 F.3d 616, 628 (4th Cir. 2015) (affirming dismissal of amended complaint where plaintiff "did not file a separate motion requesting leave to amend her complaint or attach a proposed amended complaint to her opposition brief"); *Keck v. Virginia*, 2011 WL 2708357, at *2 (E.D. Va. July 12, 2011) ("Here, Keck did not attach a copy of his proposed amended complaint for the Court's review. . . . If Keck wishes to file an amended complaint, he must seek leave to do so and submit a copy of his proposed amended complaint[.]").[5] Here, Plaintiffs have asked the Court to grant them permission to amend their complaints to add unspecified *new* allegations in their response to another party's motion to dismiss *existing* claims. This approach is inconsistent with the Rules, and Lilly cannot possibly respond to proposed amendments that Plaintiffs have described only in vague and general terms.

Plaintiffs incorrectly suggest that Judge Anderson invited them to pursue this approach in a recent hearing on Plaintiffs' motion to compel. *See* Pls.' Response at 2, 4. During the April 16, 2015 hearing, Judge Anderson merely indicated that Plaintiffs' counsel could seek the District Judge's guidance on whether Plaintiffs' proposed Rule 30(b)(6) deposition should proceed in light of Lilly's pending motion for judgment on the pleadings. *See* Apr. 16, 2015

[5] *See also Monton v. America's Servicing Co.*, 2012 WL 3596519, at *1 (E.D. Va. Aug. 20, 2012) ("Because Plaintiffs failed to attach a copy of their proposed Second Amended Complaint to their motion for leave to amend, the Court cannot analyze such proposed filing.").

Hr'g Tr. at 52:10-53:8, Bozman Decl. Ex. 2. In no way did Judge Anderson direct Plaintiffs to seek leave to amend their complaints or endorse any attempt to do so outside of the customary channels. The Court should reject Plaintiffs' attempt to fashion an end-run around normal procedures.

Second, leave to amend would not be appropriate at this late stage of the proceedings, just a few weeks shy of the close of the discovery period.[6] Although leave to amend is, under normal circumstances, "freely given," leave is not appropriate when amendment would prejudice the opposing party. *See, e.g.*, *Equal Rights Ctr.*, 602 F.3d at 603 (affirming district court's denial of motion to amend: "A district court may deny a motion to amend when the amendment would be prejudicial to the opposing party, the moving party has acted in bad faith, or the amendment would be futile."). Here, where Lilly is now just three weeks away from the discovery deadline and faces a busy schedule of remaining company witness depositions and document productions, it would be unjust to force it to shift gears and defend new failure-to-warn allegations that remain unspecified — especially when Plaintiffs waited until just a few weeks ago to seek further discovery on the capsule design issues they now concede are non-viable as pled. Plaintiffs should not be permitted to prejudice Lilly by disrupting the schedule at this late stage.

[6] In their response, Plaintiffs state that "[i]t is relatively early in the case[.]" Pls.' Response at 9. They then concede in the very next paragraph that "[d]iscovery is set to complete on May 15, 2015." *Id.*

III. Plaintiffs Should Not Be Permitted to Take a 30(b)(6) Deposition on Topics that Pertain Only to Claims and Allegations that Are No Longer in the Case.

During the recent hearing on Plaintiffs' related motion to compel,[7] Judge Anderson ruled that, if this Court were to grant Lilly's motion for judgment on the pleadings and dismiss Plaintiffs' design defect claims, Plaintiffs' proposed Rule 30(b)(6) deposition on capsule design would not proceed. *See* Apr. 16, 2015 Hr'g Tr. at 44:6-8, Bozman Decl. Ex. 2 ("THE COURT: If [Judge Trenga] grants the motion, then you won't need to do the deposition as to those topics."); *see also* Pls.' Response at 2 ("The issue of the Rule 30(b)(6) deposition was left pending by the Magistrate Judge, who ruled that, if the Court grants Lilly's motion for judgment on the pleadings, there will be no deposition."). Now that Plaintiffs have conceded that their design defect claims are preempted and have withdrawn them, Judge Anderson's ruling should apply. Because no design defect claims remain, Plaintiffs should not be permitted to conduct the proposed Rule 30(b)(6) deposition that pertains only to those claims.

Plaintiffs argue in their response that their proposed Rule 30(b)(6) topics are relevant to existing claims alleging failure to warn of alleged risks associated with tapering or discontinuation. *See* Pls.' Response at 2, 7-9. But this argument fails because the technical topics Plaintiffs have designated for their proposed 30(b)(6) deposition — the Cymbalta capsule's "enteric coating," its "capsule form," how "the pellets within the Cymbalta capsule work," and theoretical alternative doses, Pls.' Response at 3 — have no relevance to alleged required warnings concerning tapering risks of the product as designed and marketed. Simply put, the technical topics Plaintiffs seek to explore would be relevant only to design defect claims,

[7] Lilly's arguments in opposition to Plaintiffs' motion to compel are outlined in full in Lilly's response to that motion. *See generally* Def.'s Opp'n to Pls.' Mot. to Compel Two 30(B)(6) Deps. and the Dep. of Torkil Fredborg, Apr. 14, 2015, Bozman Decl. Ex. 3.

and those claims are no longer in the case. Moreover, the alleged tapering issues that Plaintiffs reference have already been the subject of considerable discovery and will continue to be addressed in scheduled depositions of corporate witnesses and experts. A Rule 30(b)(6) deposition on capsule design would thus do nothing to move this litigation forward.

Notably, Plaintiffs made this same argument — that technical capsule design topics are relevant to failure-to-warn claims — in the recent hearing before Judge Anderson, and Judge Anderson rejected it, ruling that the 30(b)(6) deposition would go forward only if the design defect claims were to remain in the case. Specifically, Plaintiffs' counsel extensively argued, across 15 pages of the hearing transcript, that "[t]he testimony from a 30(b)(6) witness about how the capsule is built, how it's created, why it has an enteric coating, how the pebbles [sic] digest in the system, and all the things that go into that are directly relevant to a failure-to-warn claim as well." Apr. 16, 2015 Hr'g Tr. at 30:16-22, Bozman Decl. Ex. 2. In response, Judge Anderson repeatedly noted that these topics relate only to alleged design defects and have no bearing on whether Lilly adequately warned of tapering- and discontinuation-related risks:

> THE COURT: Well, the topics that you have here, the design and dosing of the capsule, okay. Why was a 20-milligram dose created? Why is the Cymbalta capsule in an enteric coating? Designed — why was it put in a capsule form? How do the pellets in the capsule work in the absorption of the drug? I mean, those are all design.

Id. at 41:19-24; *see also id.* at 34:18-22 ("THE COURT: Well, I don't find that the designation that has been done in the 30(b)(6) notice would relate to the failure-to-warn claim as strongly as you are arguing here today. I think it does relate really to the design defect claim."); *id.* at 39:5-8 ("THE COURT: But I think the 30(b)(6) notice as it's been served and the topics that fall under that category really are directed towards a design defect claim and not really a warning claim."). Judge Anderson also specifically rejected Plaintiffs' argument, which they advance again in their

response, *see* Pls.' Response at 8, that a 30(b)(6) deposition on technical capsule design issues would be relevant to their claim that Lilly failed to warn of an alleged "20 mg cliff" for patients tapering off of the medicine. Apr. 16, 2015 Hr'g Tr. at 32:10-12, Bozman Decl. Ex. 2 ("THE COURT: So if you can't cut them in half, and 20 is the lowest dosage, then how could there be anything other than a 20-milligram cliff?").

As Judge Anderson repeatedly recognized, Plaintiffs' proposed 30(b)(6) topics relate only to design defect claims and have no reasonable connection to Plaintiffs' failure-to-warn claims. Given that the design defect claims no longer remain in the case, the Court should rule, consistent with Judge Anderson's prior determination, that Plaintiffs may not proceed with their proposed Rule 30(b)(6) deposition on irrelevant capsule design issues.

CONCLUSION

For the foregoing reasons, and for the reasons stated in Lilly's initial moving papers, Plaintiffs' design defect claims are preempted by federal law, and Plaintiffs have conceded the point by withdrawing those claims. The Court should dismiss the design defect claims with prejudice, and it should deny Plaintiffs' procedurally improper — and necessarily futile — request for leave to amend. The Court should also deny Plaintiffs' request to take an intrusive Rule 30(b)(6) deposition on topics that relate only to non-viable, terminated claims.

Dated April 24, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 24th day of April, 2015, I will electronically file the foregoing with the Clerk of the Court using the CM/ECF system, which will then send a notification of such filing (NEF) to the following:

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